

## IN THE CLAIMS

1. (currently amended) A tissue acquisition and fixation system comprising:  
a tissue acquisition device having an elongate main body defining a main lumen therethrough, wherein a distal end of the acquisition device is adapted to acquire tissue from within a hollow body organ and reconfigure the tissue into at least one overlap region; and  
a tissue fixation device having an articulatable cartridge assembly adapted to be advanced through the main lumen while maintaining a fixed orientation relative to the main lumen, and wherein the tissue fixation device includes a flexible shaft connected to the cartridge assembly, the flexible shaft having at least one indicator defined thereon for alignment with the acquisition device, wherein a position of the indicator relative to the acquisition device corresponds to a predetermined position of the cartridge assembly relative to the main body.
2. (original) The system of claim 1 wherein the tissue acquisition device further comprises at least two opposing members longitudinally positioned relative to one another at a distal end of the main lumen such that the cartridge assembly is stabilized from lateral movement between the at least two opposing members.
3. (canceled)
4. (currently amended) The system of claim [3] 1 wherein the flexible shaft defines at least a second indicator thereon spaced apart relative to the at least one indicator.
5. (currently amended) The system of claim [3] 1 wherein the tissue acquisition device comprises a complementary indicator thereon for corresponding alignment with the at least one indicator, wherein alignment of each indicator is indicative of when cartridge assembly is actuatable.

6. (original) The system of claim 1 wherein the tissue acquisition device further comprises at least a first acquisition member positioned at the distal end of the acquisition device.

7. (canceled)

8. (currently amended) The system of claim [7] 79 further comprising an actuation rod tubing through which the actuation rod is slidably positionable.

9. (original) The system of claim 8 wherein a distal end of the actuation rod tubing is adapted to terminate proximally of a distal end of the actuation rod, wherein the actuation rod tubing is attached near or at a distal end of the main body.

10. (original) The system of claim 1 wherein the tissue acquisition device comprises at least a first acquisition member and a second acquisition member each positionable correspondingly in apposition to one another at the distal end.

11. (canceled)

12. (canceled)

13. (original) The system of claim 10 wherein the first acquisition member and the second acquisition member are simultaneously articulatable from a first delivery configuration to a second expanded configuration.

14. (canceled)

15. (currently amended) The system of claim [14] 82 further comprising at least one vacuum tubing positioned along at least a portion of the main body, wherein the vacuum tubing is adapted to maintain fluid communication through the opening.

16. (currently amended) The system of claim [14] 82 further comprising at least one meshed basket positioned within at least one of the acquisition members.

17. (canceled)

18. (canceled)

19. (currently amended) The system of claim [18] 84 wherein at least one hinge member is angled relative to its corresponding acquisition member.

20. (canceled)

21. (canceled)

22. (original) The system of claim 1 wherein the tissue acquisition device further comprises an atraumatic distal tip.

23. (original) The system of claim 22 wherein the distal tip is tapered.

24. (canceled)

25. (canceled)

26. (original) The system of claim 1 wherein the elongate main body of the tissue acquisition device is configured to be curved.

27. (canceled)

28. (currently amended) The system of claim [27] 89 wherein the elongate main body is passively curvable via a curved stylet removably insertable within the main body.

29. (currently amended) The system of claim [27] 89 wherein the elongate main body is actively curvable via a proximally located position control.

30. (canceled)

31. (canceled)

32. (canceled)

33. (original) The system of claim 1 further comprising a handle connected to a proximal end of the main body.

34. (original) The system of claim 33 wherein the handle further comprises at least one actuation mechanism adapted to articulate the distal end of the acquisition device.

35. (canceled)

36. (canceled)

37. (currently amended) The system of claim [36] 94 wherein at least a majority of the links are adapted to pivot with respect to the adjacent link.

38. (canceled)

39. (canceled)

40. (currently amended) The system of claim [39] 96 wherein the handle is adapted to articulate the cartridge assembly from a clamped configuration to an open configuration.

41. (original) The system of claim 40 wherein the handle is further adapted to deploy a plurality of staples from the cartridge assembly.

42. (canceled)

43. (currently amended) The system of claim [42] 97 wherein the stapler housing is adapted to rotate about a pivot relative to the anvil from a clamped configuration to an open configuration.

44. (original) The system of claim 43 wherein the cartridge assembly further comprises at least one cam eccentrically connected to the stapler housing such that rotation of the cam urges the stapler housing to rotate about the pivot.

45. (original) The system of claim 44 further comprising at least one actuation cable adapted to wind about and rotate the cam via manipulation of a proximal end of the actuation cable.

46. (currently amended) The system of claim [42] 97 wherein the anvil is adapted to rotate about a pivot relative to the stapler housing from a clamped configuration to an open configuration.

47. (currently amended) The system of claim [42] 97 further comprising a plurality of staples positionable within the stapler housing.

48. (currently amended) The system of claim [42] 97 further comprising at least one wedge adapted to be translated with the stapler housing for deploying staples through corresponding apertures defined in the stapler housing.

49. (currently amended) The system of claim [42] 97 further comprising at least one staple pusher adapted to be housed within the stapler housing for contact against staples.

50. (original) A method of acquiring and affixing tissue from within a hollow body organ, comprising:

positioning a distal end of an elongate main body within the hollow body organ such that a first and a second acquisition member each positioned at the distal end are adjacent to at least one region of tissue to be acquired;

acquiring the at least one region of tissue via at least the first acquisition member;

articulating at least the first acquisition member such that the acquired tissue is approximated in contact with a tensioning member to form a folded region of tissue; and

affixing the folded region of tissue via a cartridge assembly which is adapted to maintain a predetermined orientation relative to a main lumen defined through the elongate main body.

51. (original) The method of claim 50 wherein positioning the distal end of the elongate main body comprises advancing at least one acquisition member transorally.

52. (original) The method of claim 50 wherein acquiring the at least one region of tissue comprises acquiring tissue from at least two apposed regions of tissue.

53. (original) The method of claim 50 wherein acquiring the at least one region of tissue comprises adhering the tissue to at least the first acquisition member via a vacuum created in the first acquisition member.

54. (original) The method of claim 50 wherein acquiring the at least one region of tissue further comprises acquiring a second region of tissue via a second acquisition member.

55. (original) The method of claim 54 wherein articulating at least the first acquisition member comprises articulating both the first acquisition member and the second acquisition member relative to one another such that acquired tissue is approximated between each acquisition member and corresponding tensioning members to create the folded region of tissue.

56. (original) The method of claim 55 wherein the first acquisition member and the second acquisition member are articulated simultaneously.

57. (original) The method of claim 55 wherein the first acquisition member and the second acquisition member are articulated sequentially.

58. (original) The method of claim 50 further comprising advancing the cartridge assembly through the main lumen prior to affixing the folded region of tissue, wherein the cartridge assembly cross-sectional shape is keyed to a cross-sectional area of the main lumen.

59. (original) The method of claim 50 further comprising laterally stabilizing the cartridge assembly via a yoke member positioned at the distal end of the elongate main body prior to affixing the folded region of tissue.

60. (original) The method of claim 50 further comprising advancing the cartridge assembly through the main lumen until an indicator which is defined along a flexible shaft attached to the cartridge assembly is aligned with a corresponding indicator defined proximally of the main lumen.

61. (original) The method of claim 50 wherein affixing the overlap region of tissue comprises deploying a plurality of staples from the cartridge assembly into the folded region of tissue.

62. (original) The method of claim 61 wherein deploying the plurality of staples comprises translating at least one wedge positioned within the cartridge assembly, wherein the wedge is adapted to contact and urge the plurality of staples into the folded region of tissue.

63. (original) The method of claim 50 further comprising removing the cartridge assembly from the main lumen and inspecting the folded region of tissue via an endoscopic imaging device advanced through the main lumen.

64. (original) The method of claim 50 further comprising advancing an endoscopic imaging device through the main lumen and inspecting the folded region of tissue prior to affixing the folded region of tissue.

65. (original) The method of claim 50 further comprising removing the elongate main body from the region of tissue.

66. (currently amended) A method of manipulating tissue from within a hollow body organ, comprising:

positioning a distal end of an elongate main body which defines a main lumen therethrough within the hollow body organ such that a first and a second acquisition member each positioned at the distal end are adjacent to at least one region of tissue to be acquired, wherein the main lumen is adapted to orient a cartridge assembly for passage therethrough;

advancing at least one acquisition member transorally;

acquiring the at least one region of tissue via at least the first acquisition member;

and

approximating the at least one region of tissue while maintaining the region of tissue to the first acquisition member.

67. (canceled)



68. (original) The method of claim 66 wherein acquiring the at least one region of tissue comprises adhering the tissue to at least the first acquisition member via a vacuum created in the first acquisition member.

69. (original) The method of claim 66 wherein approximating the at least one region of tissue comprises passively articulating at least one portion of the main body.

70. (canceled)

71. (original) The method of claim 66 wherein approximating the at least one region of tissue comprises actively articulating at least one portion of the main body.

72. (original) The method of claim 71 wherein actively articulating comprises manipulating the at least one portion of the main body via a proximally located position control.

73. (canceled )

74. (canceled)

75. (canceled)

76. (currently amended) The method of claim [75] 101 further comprising affixing the folded region of tissue via the cartridge assembly which is adapted to maintain a predetermined orientation relative to a main lumen defined through the elongate main body.

77. (currently amended) The method of claim [75] 101 further comprising acquiring a second region of tissue via the second acquisition member.

78. (original) The method of claim 77 further comprising articulating the second acquisition member such that the acquired tissue is approximated in contact with a second tensioning member to form a second folded region of tissue.

79. (new) A tissue acquisition and fixation system comprising:

a tissue acquisition device having an elongate main body defining a main lumen therethrough and having at least a first acquisition member positioned at a distal end of the acquisition device, the first acquisition member is articulatable via an actuation rod disposed along a length of the main body, wherein the actuation rod is manipulatable via its proximal end, and wherein the distal end of the acquisition device is adapted to acquire tissue from within a hollow body organ and reconfigure the tissue into at least one overlap region; and

a tissue fixation device having an articulatable cartridge assembly adapted to be advanced through the main lumen while maintaining a fixed orientation relative to the main lumen.

80. (new) A tissue acquisition and fixation system comprising:

a tissue acquisition device having an elongate main body defining a main lumen therethrough and having at least a first acquisition member and a second acquisition member each positionable correspondingly in apposition to one another at a distal end of the acquisition device, wherein the first acquisition member and the second acquisition member are each articulatable via a corresponding actuation rod disposed along a length of the main body, wherein each actuation rod is manipulatable via its proximal end, and wherein the distal end of the acquisition device is adapted to acquire tissue from within a hollow body organ and reconfigure the tissue into at least one overlap region; and

a tissue fixation device having an articulatable cartridge assembly adapted to be advanced through the main lumen while maintaining a fixed orientation relative to the main lumen.

81. (new) A tissue acquisition and fixation system comprising:

a tissue acquisition device having an elongate main body defining a main lumen therethrough and having at least a first acquisition member and a second acquisition member each positionable correspondingly in apposition to one another at a distal end of the acquisition device, wherein the first acquisition member and the second acquisition member are each individually articulatable from a first delivery configuration to a second expanded configuration, and wherein the distal end of the acquisition device is adapted to acquire tissue from within a hollow body organ and reconfigure the tissue into at least one overlap region; and

a tissue fixation device having an articulatable cartridge assembly adapted to be advanced through the main lumen while maintaining a fixed orientation relative to the main lumen.

82. (new) A tissue acquisition and fixation system comprising:

a tissue acquisition device having an elongate main body defining a main lumen therethrough and having at least a first acquisition member and a second acquisition member each positionable correspondingly in apposition to one another at a distal end of the acquisition device, wherein the first acquisition member and the second acquisition member each define at least one opening adapted to adhere tissue thereto via a vacuum, wherein each opening is positionable to be in offset apposition to one another, and wherein the distal end of the acquisition device is adapted to acquire tissue from within a hollow body organ and reconfigure the tissue into at least one overlap region; and

a tissue fixation device having an articulatable cartridge assembly adapted to be advanced through the main lumen while maintaining a fixed orientation relative to the main lumen.

83. (new) A tissue acquisition and fixation system comprising:

a tissue acquisition device having an elongate main body defining a main lumen therethrough and having at least a first acquisition member and a second acquisition member each positionable correspondingly in apposition to one another at a distal end of the acquisition device, wherein the first acquisition member and the second acquisition member each comprise a tensioning member adapted to be positioned adjacent to an opposing acquisition member, and wherein the distal end of the acquisition device is adapted to acquire tissue from within a hollow body organ and reconfigure the tissue into at least one overlap region; and

a tissue fixation device having an articulatable cartridge assembly adapted to be advanced through the main lumen while maintaining a fixed orientation relative to the main lumen.

84. (new) A tissue acquisition and fixation system comprising:

a tissue acquisition device having an elongate main body defining a main lumen therethrough and having at least a first acquisition member and a second acquisition member each positionable correspondingly in apposition to one another at a distal end of the acquisition device, and wherein the distal end of the acquisition device is adapted to acquire tissue from within a hollow body organ and reconfigure the tissue into at least one overlap region;

a first hinge member and a second hinge member each pivotally connecting a corresponding acquisition member to the main body; and

a tissue fixation device having an articulatable cartridge assembly adapted to be advanced through the main lumen while maintaining a fixed orientation relative to the main lumen.

85. (new) A tissue acquisition and fixation system comprising:

a tissue acquisition device having an elongate main body defining a main lumen therethrough and having at least a first acquisition member and a second acquisition member each positionable correspondingly in apposition to one another at a distal end of the acquisition device, wherein the first acquisition member and the second acquisition member are each adapted to rotate into an offset configuration such that each of the acquisition members are angled relative to a longitudinal axis defined by the main body, and wherein the distal end of the acquisition device is adapted to acquire tissue from within a hollow body organ and reconfigure the tissue into at least one overlap region; and

a tissue fixation device having an articulatable cartridge assembly adapted to be advanced through the main lumen while maintaining a fixed orientation relative to the main lumen.

86. (new) A tissue acquisition and fixation system comprising:

a tissue acquisition device having an elongate main body defining a main lumen therethrough, wherein a distal end of the acquisition device is adapted to acquire tissue from within a hollow body organ and reconfigure the tissue into at least one overlap region;

a tissue fixation device having an articulatable cartridge assembly adapted to be advanced through the main lumen while maintaining a fixed orientation relative to the main lumen; and

a guidewire for positioning the distal end of the acquisition device.

87. (new) A tissue acquisition and fixation system comprising:

a tissue acquisition device having an elongate main body defining a main lumen therethrough and having a tapered atraumatic distal tip comprised of a polymeric material, wherein a distal end of the acquisition device is adapted to acquire tissue from within a hollow body organ and reconfigure the tissue into at least one overlap region; and

a tissue fixation device having an articulatable cartridge assembly adapted to be advanced through the main lumen while maintaining a fixed orientation relative to the main lumen.

88. (new) A tissue acquisition and fixation system comprising:

a tissue acquisition device having an elongate main body defining a main lumen therethrough and having an atraumatic distal tip, wherein the distal tip defines a guidewire lumen therethrough, and wherein a distal end of the acquisition device is adapted to acquire tissue from within a hollow body organ and reconfigure the tissue into at least one overlap region; and

a tissue fixation device having an articulatable cartridge assembly adapted to be advanced through the main lumen while maintaining a fixed orientation relative to the main lumen.

89. (new) A tissue acquisition and fixation system comprising:

a tissue acquisition device having an elongate main body defining a main lumen therethrough, wherein the elongate main body of the tissue acquisition device is configured to be actively or passively curved, and wherein a distal end of the acquisition device is adapted to acquire tissue from within a hollow body organ and reconfigure the tissue into at least one overlap region; and

a tissue fixation device having an articulatable cartridge assembly adapted to be advanced through the main lumen while maintaining a fixed orientation relative to the main lumen.

90. (new) A tissue acquisition and fixation system comprising:

a tissue acquisition device having an elongate main body defining a main lumen therethrough, wherein the elongate main body of the tissue acquisition device is configured to be curved and the defines at least one bending region, and wherein a distal end of the acquisition device is adapted to acquire tissue from within a hollow body organ and reconfigure the tissue into at least one overlap region; and

a tissue fixation device having an articulatable cartridge assembly adapted to be advanced through the main lumen while maintaining a fixed orientation relative to the main lumen.

91. (new) A tissue acquisition and fixation system comprising:

a tissue acquisition device having an elongate main body defining a main lumen therethrough, wherein the elongate main body of the tissue acquisition device is configured to be uni-directionally curved, and wherein a distal end of the acquisition device is adapted to acquire tissue from within a hollow body organ and reconfigure the tissue into at least one overlap region; and

a tissue fixation device having an articulatable cartridge assembly adapted to be advanced through the main lumen while maintaining a fixed orientation relative to the main lumen.

92. (new) A tissue acquisition and fixation system comprising:

a tissue acquisition device having an elongate main body defining a main lumen therethrough, wherein the elongate main body of the tissue acquisition device is configured to be curved in a plurality of directions, and wherein a distal end of the acquisition device is adapted to acquire tissue from within a hollow body organ and reconfigure the tissue into at least one overlap region; and

a tissue fixation device having an articulatable cartridge assembly adapted to be advanced through the main lumen while maintaining a fixed orientation relative to the main lumen.

93. (new) A tissue acquisition and fixation system comprising:

a tissue acquisition device having an elongate main body defining a main lumen therethrough, wherein a distal end of the acquisition device is adapted to acquire tissue from within a hollow body organ and reconfigure the tissue into at least one overlap region;

a tissue fixation device having an articulatable cartridge assembly adapted to be advanced through the main lumen while maintaining a fixed orientation relative to the main lumen; and

a handle connected to a proximal end of the main body, the handle includes a gasket adapted to prevent fluid communication through an interior of the handle when the tissue fixation device is positioned therethrough.

94. (new) A tissue acquisition and fixation system comprising:

a tissue acquisition device having an elongate main body defining a main lumen therethrough, wherein the main body includes a plurality of adjacent links through which the main lumen is defined, and wherein a distal end of the acquisition device is adapted to acquire



tissue from within a hollow body organ and reconfigure the tissue into at least one overlap region; and

a tissue fixation device having an articulatable cartridge assembly adapted to be advanced through the main lumen while maintaining a fixed orientation relative to the main lumen.

95. (new) A tissue acquisition and fixation system comprising:

a tissue acquisition device having an elongate main body defining a main lumen therethrough and having at least two opposing members longitudinally positioned relative to one another at a distal end of the main lumen, wherein each of the two opposing members are adapted to flex via a plurality of pivots, and wherein a distal end of the acquisition device is adapted to acquire tissue from within a hollow body organ and reconfigure the tissue into at least one overlap region; and

a tissue fixation device having an articulatable cartridge assembly adapted to be advanced through the main lumen while maintaining a fixed orientation relative to the main lumen, wherein the cartridge assembly is stabilized from lateral movement between the at least two opposing members.

96. (new) A tissue acquisition and fixation system comprising:

a tissue acquisition device having an elongate main body defining a main lumen therethrough, wherein a distal end of the acquisition device is adapted to acquire tissue from within a hollow body organ and reconfigure the tissue into at least one overlap region; and

a tissue fixation device having an articulatable cartridge assembly adapted to be advanced through the main lumen while maintaining a fixed orientation relative to the main lumen, and the tissue fixation device includes a handle connected to the cartridge assembly via a flexible shaft.

97. (new) A tissue acquisition and fixation system comprising:

a tissue acquisition device having an elongate main body defining a main lumen therethrough, wherein a distal end of the acquisition device is adapted to acquire tissue from within a hollow body organ and reconfigure the tissue into at least one overlap region; and

a tissue fixation device having an articulatable cartridge assembly adapted to be advanced through the main lumen while maintaining a fixed orientation relative to the main lumen, the cartridge assembly includes a stapler housing and an anvil in apposition to the stapler housing.

98. (new) A method of manipulating tissue from within a hollow body organ, comprising:

positioning a distal end of an elongate main body which defines a main lumen therethrough within the hollow body organ such that a first and a second acquisition member each positioned at the distal end are adjacent to at least one region of tissue to be acquired, wherein the main lumen is adapted to orient a cartridge assembly for passage therethrough;

acquiring the at least one region of tissue via at least the first acquisition member; and

approximating the at least one region of tissue while maintaining the region of tissue to the first acquisition member and passively articulating at least one portion of the main body by removably inserting a curved stylet within a length of the main body.

99. (new) A method of manipulating tissue from within a hollow body organ, comprising:

positioning a distal end of an elongate main body which defines a main lumen therethrough within the hollow body organ such that a first and a second acquisition member

each positioned at the distal end are adjacent to at least one region of tissue to be acquired, wherein the main lumen is adapted to orient a cartridge assembly for passage therethrough;

acquiring the at least one region of tissue via at least the first acquisition member;

and

approximating the at least one region of tissue while maintaining the region of tissue to the first acquisition member and uni-directionally curving the at least one portion of the main body via a proximally located position control.

100. (new) A method of manipulating tissue from within a hollow body organ, comprising:

positioning a distal end of an elongate main body which defines a main lumen therethrough within the hollow body organ such that a first and a second acquisition member each positioned at the distal end are adjacent to at least one region of tissue to be acquired, wherein the main lumen is adapted to orient a cartridge assembly for passage therethrough;

acquiring the at least one region of tissue via at least the first acquisition member;

and

approximating the at least one region of tissue while maintaining the region of tissue to the first acquisition member and curving the at least one portion of the main body via a proximally located position control in a plurality of directions.

101. (new) A method of manipulating tissue from within a hollow body organ, comprising:

positioning a distal end of an elongate main body which defines a main lumen therethrough within the hollow body organ such that a first and a second acquisition member each positioned at the distal end are adjacent to at least one region of tissue to be acquired, wherein the main lumen is adapted to orient a cartridge assembly for passage therethrough;

acquiring the at least one region of tissue via at least the first acquisition member;

approximating the at least one region of tissue while maintaining the region of tissue to the first acquisition member and actively articulating at least one portion of the main body via a proximally located position control; and

articulating at least the first acquisition member such that the acquired tissue is approximated in contact with a tensioning member to form a folded region of tissue.